

DEVICES AND METHODS FOR FACILITATING CONTROLLED BONE GROWTH OR REPAIR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of co-pending International Application No. PCT/US02/23262, filed July 23, 2002, which International Application designates the United States and which itself is a continuation-in-part of U.S. Patent Application Serial No. 09/737,074, filed December 14, 2000, now abandoned, to which priority is claimed.

BACKGROUND OF THE INVENTION

Technical Field:

[0002] This invention is directed generally to devices and methods for facilitating bone growth, and, in particular, to bone implantable devices and implantation methodologies that augment beneficial bone growth or repair while limiting bone growth in undesirable directions.

Background:

[0003] In orthopedic and neurological surgical procedures it is often important to facilitate the growth or fusion of bony structures. This may entail growth “bone-to-bone” or, depending on the nature of the procedure, bone to device.

[0004] Chronic back problems, for example, cause pain and disability for a large segment of the population. In many cases, such problems are attributable to relative movement between vertebrae in the spine. Spinal surgery includes procedures to stabilize adjacent vertebrae. Common stabilization methods often involve fusing adjacent vertebrae together.

[0005] Fusion techniques include removing disc material that separates the vertebrae and impacting bone into the disc area. The impacted bone fuses with the bone material of the two adjacent vertebrae to thereby fuse the vertebrae together.

[0006] In a further advance in the art, spinal implants have been developed to increase the probability of a successful fusion. Such devices generally comprise a hollow cage into which bone growth inducing substances, such as bone chips or bone slurry, may be placed. The cage is inserted, either by anterior or posterior approach, into the intervertebral disc space. The cage wall has holes extending radially therethrough, typically throughout the entire cage surface. Bone growth extends into the device through the radial apertures, facilitating arthrodesis between the adjacent vertebral bone structures and allowing for the decompression of neural elements.

[0007] With the continued development of techniques for achieving spinal fusion through the use of spine fusion cages, new materials have been developed to augment the fusion process. Traditionally, the patient's own bone, or cadaver bone, was used in the cage to promote bony fusion. More recently, powerful new biologic materials have been discovered that greatly accelerate the fusion process, in some cases eliminating the need for donor bone.

[0008] However, with the utilization of the newer biologic materials there has arisen a significant problem. When bone growth inducing agents, such as bone morphogenic proteins ("BMP"), are used in cages of existing design there is risk of inducing the overgrowth of bone around and into sensitive neural tissues. This is especially the case when a posterior approach is utilized to implant a spinal fusion cage, as bony overgrowth toward the central canal or neural foramen may impinge on spinal nerve roots causing neurological damage. A recent study on posterior lumbar interbody

fusion procedures using rhBMP-2 reported that 58% of patients experienced greater than expected bone formation dorsal to the fusion cage. In 30% of the cases, the bony overgrowth compromised the central canal, the neural foramen, or both. This study is confirmatory to observations first made by the present inventor in early 1999.

[0009] Typically, the bone growth agent is in liquid form and is applied to an absorbent carrier material, such as a piece of bovine collagen. The doped carrier material is placed with forceps into the interbody space, usually into an open end of the fusion cage after the cage has been implanted, but sometimes prior to cage implantation. During placement carrier material may inadvertently wipe across body areas, including internal bony structures, where bone growth is not desired. In addition, as the carrier material is pressed into place agent may squeeze out and flow into adjacent areas. Exacerbating the problem, current protocols do not encourage the use of suction, irrigation and hemostatic agents when bone growth agent is utilized. Conventional cage design also allows for the leakage of agent into undesirable areas after implantation through ill-placed apertures in the cage body, in the cage end caps, or otherwise. Because of the powerful stimulatory effects of bone growth agents, uncontrolled application of these substances may lead to serious complications, including severe inflammation, debilitating neural impingement, and other potential complications.

[0010] Thus, there is a need to better control the bone growth process when using a bone implantable device, especially in circumstances where powerful bone growth inducing agents are used in conjunction therewith.

[0011] In satisfying this need, there is also an opportunity to extend the application of bone growth agent based bony fusion to all types of bone implantable devices to better achieve union of bone-to-bone or bone-to-device, as the case may be.

SUMMARY OF THE INVENTION

[0012] In connection with the present invention, there are provided bone implantable devices and implantation methodologies that allow for the careful application of bone growth inducing agents, *e.g.* BMP, and management of bone growth processes.

[0013] In accordance with one aspect of the present invention, there is provided a bone implantable device and carrier combination, which combination is implanted into the body prior to application of bone growth agent to the carrier. After the device is implanted, the bone growth agent may be applied to the carrier in a manner avoiding its contact with non-target body structures.

[0014] In one embodiment the bone implantable device includes a conveniently placed injection port that communicates with the carrier material. After implantation of the device bone growth agent is applied to the carrier material through the injection port.

[0015] In another embodiment, the bone implantable device includes a hollow interior structure in which carrier material is located. After implantation of the device the bone growth agent is injected into the carrier material through an injection port. One or more apertures communicating with the hollow interior are located on the portion of the device that is, upon implantation, adjacent target bone structure, allowing for the controlled delivery of bone growth agent to the target bone structure.

[0016] In still another embodiment, a plenum is provided in the hollow interior of a bone implantable device to facilitate the even distribution of bone growth agent from the injection port into the carrier material.

[0017] The bone implantable device may take the form of an interbody spinal fusion cage, a facet fusion screw, an artificial joint, a bone fixation plate, an intervertebral body graft, an IM nail, a hip stem, and other orthopedic appliances where promoting bone-to-bone growth or growth from bone into the device is beneficial. The bone implantable device itself is so constructed as to allow the bone growth agent to flow therefrom only in desired directions, *i.e.* to target bone structures. Many non-limiting examples are provided herein for illustrative purposes.

[0018] As primary examples of device construction for vertebral fusion purposes, there are provided several embodiments of a fusion cage which can be inserted into an intervertebral disc space using either a posterior or anterior approach and which prevents overgrowth of bone around or into neural tissue. Growth of bone into sensitive areas is prohibited by providing the cage with various zones wherein the cage wall is either perforated or non-perforated. A cage body is provided having a posterior end and an anterior end and defining an internal cavity and a longitudinal axis. The cage body has an outer surface and a plurality of apertures extending from the outer surface and communicating with the internal cavity in a preselected pattern. Preferably, there is a first non-perforated zone extending from the posterior end of the cage a preselected length toward its anterior end, second and third non-perforated zones on the longitudinal sides, wherein non-perforated zones are defined by the medial sides of the cage extending in opposing relation from the first zone further toward the anterior end, and two opposed perforated zones oriented so that upon insertion of the device the perforated zones will be adjacent the vertebral bodies to be fused, which channels the bone growth in a superior and inferior direction only to allow bone growth across the vertebral interspace. Each end of the cage is provided with a non-perforated closure. Preferably, the posterior end is

closed completely, while the anterior end may or may not be closed. In this manner bone growth is prevented in areas adjacent the non-perforated zones when the fusion cage is in place.

[0019] In another example there is provided a novel spine fusion cage which provides for the selective occlusion of apertures in the cage wall so as to prevent the growth of bone in undesired directions. As an example, there is provided an inventive cage having outer and inner cage elements. An outer cage body having a posterior end and an anterior end defines an internal cavity. A plurality of apertures extends through the outer surface of the outer cage body to communicate with the internal cavity in a pattern covering a substantial portion of the outer surface of the cage body. An inner cage body is disposed within the internal cavity of the outer cage body and is positioned as to form an annulus between the inner wall surface of the outer cage body and the outer wall surface of the inner cage body. The inner cage body likewise has a plurality of apertures extending through its outer surface so as to establish communication with the annulus and the outer surface of the outer cage. An end closure means having occluding surfaces suitable for introduction into the annulus between the outer and inner cages serves to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the outer cage body, thereby obstructing bone growth in undesired directions.

[0020] In still another example there is provided an end closure means for effecting the closure of the posterior end of a fusion cage while establishing a desired occlusion pattern of apertures in the wall of the fusion cage. The closure means comprises a non-perforated sealing member to effect the closure of the posterior end of the internal cavity of the fusion cage and one or more occluding surfaces extending from

the sealing member essentially parallel to the longitudinal axis of the fusion cage so as to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the cage body.

[0021] In still another example, a cage body is provided that has a posterior end and an anterior end and defines an internal cavity. The cage body further has an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity, wherein the outer surface has a preselected pattern of perforated and non-perforated zones. A first end closure is secured at a first end of said cage body. A second end closure is provided that has an orifice therein. The second end closure is secured at a second end of the cage body. At least one of the first end closure and the second end closure is removable so as to provide access to the internal cavity. A plug is located in the orifice that is capable of being penetrated by a syringe needle for administering a bone growth agent to said internal cavity. Preferably, a carrier that is compatible with a bone growth or biologic agent and that holds and dispenses the agent in a time released and controlled fashion, receives the bone growth agent. By using this approach, chances for misapplication of bone growth material are greatly diminished. A plenum is preferably used to encourage even application of the bone growth agent to the carrier material.

[0022] Further examples as related to other orthopedic appliances are also provided.

[0023] In addition, in accordance with another aspect of the present invention there is provided a methodology for implanting bone implantable devices wherein the device and carrier material are implanted into the body in their operative positions prior to the loading of bone growth agent into the carrier material.

[0024] In one embodiment, the carrier material is isolated within the bone implantable device prior to application of the bone growth agent to the carrier material.

[0025] In a preferred embodiment, the bone growth agent is applied to the carrier material via an injection port.

[0026] In another preferred embodiment, bone growth agent is applied to the carrier material through a plenum communicating with an injection port.

[0027] A better understanding of the present invention, its several aspects, and its advantages will become apparent to those skilled in the art from the following detailed description, taken in conjunction with the attached drawings, wherein there is shown and described the preferred embodiments of the invention, simply by way of illustration of the best mode contemplated for carrying out the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. 1 anatomically illustrates a bilateral posterior insertion of two inventive spine fusion cages to achieve fusion across the L5/S1 disc space.

[0029] FIG. 2 is an exploded perspective view of an embodiment of an inventive cage having preselected perforated and non-perforated zones on its outer surface.

[0030] FIG. 3 is a perspective view taken along line 3-3 of FIG. 2.

[0031] FIG. 4 is a sectional view taken along line 4-4 of FIG. 2.

[0032] FIG. 5 is perspective view of an embodiment of an inventive cage having outer and inner cage elements.

[0033] FIG. 6 is a sectional view taken along line 6-6 of FIG. 5.

[0034] FIG. 7 is a perspective view of an end closure for use in connection with

the cage of FIG. 5.

[0035] FIG. 8 is a top sectional view of the cage of FIG. 5 including the end closure of FIG. 7.

[0036] FIG. 9 is an exploded side view of a conventional fusion cage modified to utilize an inventive end closure means to selectively occlude certain apertures in the outer surface of the cage.

[0037] FIG. 10 depicts the partial insertion of the inventive closure means into the cage of FIG. 9.

[0038] FIG. 11 depicts the full insertion of the inventive closure means into the cage of FIG. 9.

[0039] FIG. 12 is top sectional view of a modified conventional cage including an inventive end closure means.

[0040] FIG. 13 is an exploded perspective view of an embodiment of an inventive cage having an end cap and an injection port.

[0041] FIG. 14 is a partial cross-sectional view of an embodiment of a bone implantable device shown located within a bone structure.

[0042] FIG. 15 is a cross-sectional view of an embodiment of a bone implantable structure shown functioning as a ball portion of a ball and socket joint.

[0043] FIG. 16 is a cross-sectional view of the embodiment of FIG. 15 taken along line 16 – 16 of FIG. 15.

[0044] FIG. 17 is a side view of an artificial joint fused to adjacent vertebrae.

[0045] FIG. 18 is a cross-sectional view taken along lines 18 – 18 of FIG. 17.

[0046] FIG. 19 is a partial cross-sectional view of a bone implantable structure for use as a spinal fusion cage wherein the spinal fusion cage has a plenum member located

therein.

[0047] FIG. 20 is a perspective view of the plenum member of FIG. 19.

[0048] FIG. 21 is a cross-sectional view taken along line 21 – 21 of FIG. 19.

[0049] FIG. 22 is a perspective view of a bone implantable structure for use as an intervertebral body graft.

[0050] FIG. 23 is a top view of the intervertebral body graft of FIG. 22.

[0051] FIG. 24 is a cross-sectional view of the intervertebral body graft of FIG. 22.

[0052] FIG. 25 is a side view of a bone implantable structure located on a bone structure.

[0053] FIG. 26 is a top view of the bone implantable structure of FIG. 25.

[0054] FIG. 27 is an enlarged perspective view of the bone implantable structure of FIG. 27.

[0055] FIG. 28 is a perspective view of another embodiment of the spinal fusion cage.

[0056] FIG. 29 is a partial cross-sectional view of a “360° fusion” vertebral fusion including the spinal fusion cage of FIG. 19 and a facet fusion screw engaging adjacent vertebral facets.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0057] Before explaining the present invention in detail, it is important to understand that the invention is not limited in its application to the details of the construction illustrated and the steps described herein. The invention is capable of other

embodiments and of being practiced or carried out in a variety of ways. It is to be understood that the phraseology and terminology employed herein is for the purpose of description and not of limitation.

[0058] As used herein the phrases “bone growth inducing agent(s),” “bone growth agent(s),” “bone growth accelerator”, “bone morphogenic protein(s),” and “BMP” refer synonymously to any substance useful in stimulating bone growth, whether a protein or not. Such substances are well known in the art.

[0059] As used herein the terms “carrier” and “carrier material” refer synonymously to any material capable of absorbing or otherwise holding or containing a bone growth inducing agent and which allows for the delivery of such agent to a target bone structure.

[0060] In the preferred embodiment of the present invention, a bone implantable device and carrier combination is implanted into the body prior to application of bone growth agent to the carrier. As indicated in the various example embodiments disclosed herein, the device may take a variety of forms. Typically, the device is made from titanium, alloys of titanium, Carbon fiber, bone or ceramic, but it may be made of any suitably strong material tolerated by the body. The device may comprise a unitary structure or may be of a multi-piece construction. In certain applications it may be advantageous to include a removable end cap or cover to allow access to the interior of the device. Further, the device or portions of the device, such as an end cap or other component may be constructed of a bio-absorbable material.

[0061] The device is preferably pre-loaded with carrier material, which may be retained in a hollow within the device or otherwise retained, such as adhesively, to an outside surface portion of the device. After the device and carrier combination is

implanted, bone growth agent is applied to the carrier in a manner avoiding its contact with non-target body structures.

[0062] As bone growth agent is conventionally applied in liquid form, several preferred embodiments of the bone implantable device include a conveniently placed injection port that communicates with the carrier material. A plenum may be used to confine the flow of the bone growth agent from the injection port to the carrier material and to obtain even saturation of the material.

[0063] Besides enabling the better handling of the bone growth agent during the surgical procedure, the inventive bone implantable device better manages the stimulated bone growth by providing, in effect, one or more artificial tissue planes that prevent bony overgrowth in undesirable directions. The device allows bone growth agent to elute to the target bone structure, preferably through pathways or openings directly contacting the target bone structure, but the bone growth agent is otherwise confined in the device. The device walls prevent leakage of the bone growth agent toward sensitive areas or structures.

[0064] Bone implantable devices and implantation methodologies of the invention allow for the careful application of biologically active substances, such as bone growth accelerants including bone morphogenic proteins (BMP) for management of bone growth processes. Although bone growth accelerants are referred to in the below examples, it should be understood that the bone implantable devices of the invention may be used to deliver other biologically active substances as well. As will be discussed below, the bone implantable device of the invention may take the form of interbody spinal fusion cages, facet fusion screws, artificial joints, bone fixation plates, interbody grafts, e.g. intervertebral body grafts, IM nails, hip stems, and other orthopedic appliances

where promoting bone-to-bone growth or growth from bone into the device is beneficial.

Additionally, it is contemplated that the bone implantable devices of the invention may be used to deliver substances to enhance the growth of cartilage, tendon and other body structures in addition to bone.

[0065] The present invention will be further understood with reference to the following non-limiting examples.

EXAMPLE 1 – Spine Fusion Cages

[0066] Several types of conventional spine fusion cages have been designed, such as those described by Bagby, Brantigan and Ray, respectively, in *Athrodesis by the Distraction-Compression Method Using a Stainless Steel Implant*, Orthopaedics 1988, Vol. 11:931-4; *A Carbon Fibre Implant to Aid Interbody Lumbar Fusion*, Spine 1991, 16 (Suppl):S277-82 (with Steffee and Geiger); and *Threaded Titanium Cages for Lumbar Interbody Fusions*, Spine 1997, 22:667-80; and as described in the patent art, for example, in U.S. Patent Nos. 4,501,269; 5,055,104; 5,571,192; 5,702,449; 5,876,457; 5,906,616; 5,976,187; 5,980,522; 6,010,502; 6,015,436; and 6,039,762. Each of the foregoing publications and patents is incorporated herein by reference.

[0067] Such devices provide for a relatively simple and effective technique for implementing lumbar interbody fusion by correcting any existing mechanical deformity of the spine while providing stability and a good environment until successful arthrodesis is obtained. These cage devices are hollow and are positioned between the articulating vertebrae, where they support and immobilize the joint as well as contain the growth of the bone graft that is packed into the internal cavity of the device.

[0068] Anterior lumbar interbody fusion (ALIF) and posterior lumbar interbody fusion (PLIF) are two commonly adopted approaches for grafted lumbar interbody fusion

with augmentation via a spine fusion cage. ALIF is performed through a retroperitoneal or transperitoneal approach with extensive discectomy followed by the placement of one or more cages in the vertebral interspace. In PLIF, partial or complete laminectomy and facetectomy is followed by posterior discectomy and the placement of one or more cages in the vertebral interspace. FIG. 1 is illustrative of a bilateral posterior insertion of two inventive spine fusion cages **20** to achieve fusion across the L5/S1 disc space. The cages **20** are secured far enough apart from each other (by a few millimeters) to avoid contact and potential back-threading. It should be understood that the fusion cages of this invention can be installed in their operative positions via either the anterior or posterior approaches; however, the posterior approach is the most dangerous in regards for bony overgrowth impinging on neural tissue particularly when the cage is used along with bone growth inducing materials.

[0069] The inventive cages **20** promote bony fusion by holding adjacent levels immobile and by allowing bone to grow only into the vertebral bodies and away from the spinal canal and nerve roots. Designs that do not control direction of growth are undesirable for use with biologic bone growth agents to the extent unchecked bony overgrowth may impinge upon neural tissues. Through the present invention there are provided designs for spine fusion cages which prevent bone growth around and into sensitive areas of neural tissue.

[0070] Referring now to FIGs. 2 - 4, and in accordance with one embodiment of the present invention, there is provided an inventive spine fusion cage **20** wherein growth of bone into sensitive areas is prohibited by providing the cage with various zones or areas wherein the cage wall is either perforated or non-perforated. A cage body **22** is provided having a posterior end **24** and an anterior end **26** and defining an internal cavity

28 and a longitudinal axis **30**. The cage body **22** is typically between 20-25 mm in length and may be of a variety of diameters, dimensions and heights. The cage body **22** has an outer surface **32** and a plurality of radial apertures **34** or pathways extending through the outer surface **32** in communication with the internal cavity **28** in a preselected pattern. Preferably, there is a first non-perforated zone **36** extending from the posterior end **24** of the cage body **22** a preselected length, preferably 5-10 mm, toward its anterior end **26**, second and third non-perforated zones **38, 40** on the lateral sides of the cage body **22** extending in opposing relation from the first zone **36** further toward the anterior end **26**, and two opposed perforated zones **42, 44** oriented cephalad (or to the superior side) and caudad (or to the inferior side) so that upon insertion of the device the perforated zones **42, 44** will be adjacent the vertebral bodies to be fused to allow bone growth across the vertebral interspace. Ends **24, 26** of the cage body **22** are provided with a non-perforated closure. In the illustrated embodiment, the anterior end **26** is closed by an integral non-perforated end wall **46**, while there is provided a removable end cap **48** securable, by threaded attachment, friction fit or otherwise, to the posterior end **24** of the cage body **22**. The end cap **48** may be provided with a recess **50** for receiving an insertion tool, for example if the end cap is made to threadably connect to the cage body, and there is preferably provided on the top of the end cap **48** a line score **52** for aiding proper orientation of the device in the vertebral interspace.

[0071] The cage body **22** may be provided with threads **54**, projections, ridges, protrusions, barbs, spurs or other insertion means to aid in placement of the cage within the interbody area. The anterior end **26** can be rounded in order to facilitate the insertion of the cage **20** relative to one or more bone structures. The cage **20** may be made of surgical steel, titanium or other acceptable implantable materials. Typically, the cage **20**

is countersunk into the vertebral interspace with the end cap **48** in place by using an insertion tool (not shown) to screw the cage **20** into position. Once the cage is properly aligned, the end cap **48** is removed so that bone growth inducing material can be packed into the internal cavity **28** of the cage body **22**, whereupon the end cap **48** is tightly replaced.

[0072] As can now be appreciated, the inventive cage **20** prevents bone growth into areas adjacent the non-perforated zones when the fusion cage is in place. Because the posterior 5-10 mm of the cage is non-perforated, including, importantly, the end cap, bony overgrowth is inhibited in areas immediately adjacent the posteriorly located neural tissues. In similar fashion, lateral overgrowth of bone is impeded by the second and third non-perforated zones. Desired growth through the vertebral interspace, however, is facilitated via the perforated zones.

[0073] It should be understood to be within the ordinary skill of one in the art to modify the placement of the various perforated and non-perforated zones as warranted by orthopaedic considerations to achieve desired bone growth and preclude unwanted bone growth. It is also within the ordinary skill of one in the art to modify the aforescribed device for anterior insertion procedures by providing a removable end cap on the anterior end of the cage body and reversing the thread direction on the outside surface of the cage body.

[0074] As mentioned above, it is also advantageous for a surgeon to have the ability to selectively occlude apertures in the cage wall to prevent bone growth in undesired directions. Now referring to FIGs. 5 - 8, to achieve this object, and in accordance with another embodiment of the present invention, there is provided a spine fusion cage **120** having an outer cage body **122** with a posterior end **124** and an anterior

end 126 and defining an internal cavity 128 and a longitudinal axis 130. The outer cage body 122 has an outer surface 132 and a plurality of radial apertures 134 extending through the outer surface 132 in communication with the internal cavity 128 in a pattern covering a substantial portion of the outer surface 132 of the cage body 122. An inner cage body 136 into which is placed bone growth inducing substances is disposed within the internal cavity 128 of the outer cage body 122 and is positioned as to form an annulus 138 between the inner wall surface 140 of the outer cage body 122 and the outer wall surface 142 of the inner cage body 136. The inner cage body 136 likewise has a plurality of radial apertures 144 extending through its outer surface 142 so as to establish communication with the annulus 138 and the outer surface 132 of the outer cage body 122. A solid end closure 146 having opposed occluding surfaces 148, 150 suitable for introduction into the annulus 138 serves to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the outer cage body 122, thereby obstructing bone growth in undesired directions.

[0075] More specifically, as shown in FIG. 7 end closure 146 is comprised of a non-perforated cap or closure means 152 having occluding surfaces 148 and 150 extending therefrom. Such surfaces may be of sufficient length to extend to the bottom of the cage member 120 as shown in FIG. 5 or may be of a more limited length so as to occlude only a portion of the apertures 134 in the outer cage body 122. The end closure 146 may be constructed so as to provide a top circumferential crown portion 154 and between the occluding surfaces 148, 150 a shoulder 156 which may engage a rib means 158, 160 as shown in FIG. 8 to act as a longitudinal stop and to limit the degree of rotation which can be made by occluding surfaces 148, 150 so as to maintain the selected occlusion pattern. When positioned within the annulus 138 of the fusion cage 120, the

occluding surfaces 148, 150 serve to close openings in the posterior end of the cage 120 as well as to occlude openings or pathways which are in a lateral position so as to effect bone growth through the apertures in the caudal and cephalad directions when placed in the desired position between two vertebrae. Various interchangeable forms of end closures may be provided, for example having differently shaped and dimensioned occluding surfaces, so as to provide for the surgeon a selection which meets objectives according to various orthopaedic exigencies. It is also within the scope of this invention that the shape and dimensions of the occluding surfaces may be modifiable by the surgeon, such as if the occluding surfaces comprise a surgical plastic adapted to be cut or trimmed to achieve a desired configuration. In this manner, a cage possessing a full pattern of apertures can be used as a "universal" cage in combination with one of a wide selection of end closures or a modifiable end closure to achieve any desired patterned of perforation.

[0076] The end closure 146 can be threaded or otherwise designed to effect the closure of the posterior end of the cage 120 and may be provided with securing means such as square or hex-shaped recess 162 which can be used with a socket wrench to tightly position the end closure 146 in the posterior end of the fusion cage 120. In complementary fashion, threads may be provided at the posterior end of the cage 120 to receive a threaded end closure 146 or it can be so adapted that the end closure 146, when not threaded, can be simply snapped into place to effect the desired closing of the fusion cage 120.

[0077] A thread 164 may be provided as part of the outer surface 132 of the fusion cage 120. Such a thread can be replaced with a plurality of discrete threads or a

plurality of projections, ridges, protrusions, barbs or spurs and be within the spirit and scope of the invention.

[0078] In assembly of the fusion cage of this embodiment of the invention, following introduction of the selected biologic material into the internal cavity **128** within the inner cage body **136**, the annulus **138** remains clear so as to easily accept end closure **146** within the annulus **138** while the biologic materials are retained in the internal cavity **128**. Through the dimensioning, shaping and rotation of occluding surfaces **148**, **150** there is achieved an occlusion of apertures so as to define the desired pattern of apertures through which bone growth is to be permitted.

[0079] In keeping with the teachings of the present invention, there is further provided a novel closure for conventional spine fusion cages which can be used with little or no modification to presently available fusion cages in preventing bone growth into undesirable areas. This embodiment involves providing a means for the occlusion of selected apertures in currently available fusion cages, such as to those commonly referred to as Brantigan, BAK and Ray cages, so that bone growth is directed only toward the vertebral bodies and away from the spinal canal and nerve roots.

[0080] Making reference now to FIGs. 9 - 11, there is illustrated an end closure **220** for effecting the closure of the posterior end **222** of a conventional fusion cage body **224** while establishing a desired occlusion pattern of apertures in the wall of the cage body **224**, which cage possesses apertures **226** substantially entirely thereabout. The end closure **220** comprises a non-perforated sealing member **228** to effect the closure of the posterior end **222** of the cage body **224** and one or more occluding surfaces **230**, **231** extending from the sealing member **228** essentially parallel to the longitudinal axis **230** of the cage body **224** so as to establish one or more desired zones or patterns of occluded

apertures amongst the plurality of apertures in the cage body **224**. Reference is made to the disclosure provided above with respect to the aforescribed end closure **146**, which disclosure is equally applicable to end closure **220** and further recitation is believed unnecessary. Suffice it to say that the prior described end closure **146** may be made adaptable to conventional fusion cages so as to achieve the objectives of the present invention.

[0081] As depicted in FIG. 12, if desired the conventional type of fusion cage can be so modified as to provide ribs **232**, **234** in association with the inner surface of the posterior end of the cage according to the teachings herein. FIG. 12 provides a top view of the fusion cage of FIG. 11 along the line 12-12 which shows the placement of the ribs **232** and **234** to accommodate occluding surfaces **230**, **231** of the end closure **220**.

[0082] Referring now to FIG. 13, an exploded view of an embodiment of an inventive cage **300** is shown having an end cap **302** and an end cap **304** having an orifice **306**. Orifice **306** is preferably sealed with a plug **308**, e.g. a silicone plug or a plug of another material capable of being penetrated by a syringe needle to dope a carrier **310**. Carrier **310** is provided to receive bone growth accelerants, such as bone morphogenic proteins, and is located in the interior of cage **300**. A preferred carrier **310** is a sponge type material such as bovine collagen sponge or any type of collagen that will bind to bone growth accelerator. In use, the cage **300** is desirable because cage **300** may be located within a patient prior to loading cage **300** with bone growth accelerants. Locating cage **300** prior to loading the bone growth accelerator prevents bone growth accelerator from inadvertently contacting areas of the patient that are not intended to experience bone growth. After the cage **300** is located, bone growth accelerator may be carefully administered via a syringe needle, which is pushed through plug **308**. Once the syringe

needle has penetrated plug 308, bone growth accelerant may be delivered to the carrier 310, e.g. sponge material. By doping the carrier material 310 in this way, the risks associated with locating a cage 300 filled with bone growth accelerant are minimized. Additionally, the bone growth accelerant may be pre-loaded onto the carrier material 310 in a dissolvable form, e.g., a crystalline form, gel or other form that will eventually migrate outside of cage 300 once implanted into a human body and exposed to body fluids, body heat, etc. Of course, a dissolvable form of carrier material may be utilized in any of the examples of the invention as desired.

[0083] Referring now to FIG. 28 a partial cross-sectional view of a rectangular embodiment of an inventive cage 350 is shown having a first end 352 and a second end 354. Second end 354 defines an orifice 356. Splines 358 are provided to assist in securing cage 350 in a desired location. Orifice 356 is preferably sealed with a plug, e.g. a silicone plug or a plug of another material capable of being penetrated by a syringe needle to dope a carrier material 360. Holes 361 are used to manipulate cage 350 during placement of cage 350. Carrier 360 is provided to receive bone growth accelerants, such as bone morphogenic proteins, and is located in the interior of cage 350. A preferred carrier 360 is a sponge type material such as bovine collagen sponge or any type of collagen that will bind to bone growth accelerant. In use, the cage 350 may be located within a patient prior to loading cage 350 with bone growth accelerants. Locating cage 350 prior to loading the bone growth accelerant prevents bone growth accelerant from inadvertently contacting areas of the patient that are not intended to experience growth. After the cage 350 is located, bone growth accelerant may be carefully administered through orifice 356. Preferably, bone growth accelerant is delivered via a syringe needle, which is pushed through a plug located within orifice 356. Once the syringe needle has

penetrated the plug, bone growth accelerator may be delivered to the carrier **360**, e.g. sponge material. By doping the carrier material **360** in this way, the risks associated with locating a cage **350** filled with bone growth accelerator are minimized. Additionally, bone growth accelerator may be pre-loaded onto the carrier material **360** in a dissolvable form, e.g., a crystalline form, gel or other form that will eventually migrate outside of cage **350** once implanted into a human body and exposed to body fluids, body heat, etc. Bone growth accelerator passes through pathways or orifices **370** to contact target bone material.

[0084] As a further example of a bone implantable device of the invention, an exploded view of an embodiment of an inventive cage **400** is shown in FIGs. 19 and 21 having an end cap **404** defining an orifice. The orifice is preferably sealed with a plug **408**, e.g. a silicone plug or a plug of another material capable of being penetrated by a syringe needle. A carrier **410** for a bone growth accelerator, such as bone morphogenic protein, is located in the interior of cage **400**. A preferred carrier **410** is compatible with a bone growth or biologic agent and holds and dispenses the agent in a time released and controlled fashion. An example of a suitable carrier **410** is a bovine collagen material. In use, the cage **400** may be located within a patient prior to loading cage **400** with bone growth accelerants. Placement of cage **400**, e.g., between adjacent vertebra as shown in FIG. 29, prior to loading the bone growth accelerator prevents bone growth accelerator from inadvertently contacting areas of the patient that are not intended to experience bone growth. After the cage **400** is located, bone growth accelerator may be carefully administered through the orifice defined by end cap **404**. A preferred method is via a syringe needle, which is pushed through plug **408**. Once the syringe needle has penetrated plug **408**, bone growth accelerator may be delivered into plenum **409**, which assists in evenly distributing the bone growth accelerator to the carrier **410**, i.e., assists in

doping carrier 410. As shown in FIGs. 19 and 20, plenum 409 is provided with a plurality of pathways or orifices 411 through which the bone growth accelerant may migrate into carrier 410. Preferably, orifices 411 are distributed over the length of plenum 409 such that a greater concentration of orifices may be found on an end of the plenum opposite plug 408. The unequal distribution of orifices 411 over the length of plenum 409 is designed to compensate for a disparity in the amount of bone growth accelerant delivered into the plenum 409. Alternatively, orifices 411 may be smaller at one end and larger at an end of the plenum 409 opposite plug 408. In either case, an orifice area near an end of the plenum 409 opposite plug 408 is preferably greater than an orifice area on plenum 409 nears plug 408. The desired result is for the bone growth accelerant to migrate into carrier 410 in a uniform distribution over the length of carrier 410.

[0085] Referring now to FIG. 29, a transarticular screw, such as facet fusion screw 420 is shown as yet another example of a bone implantable device of the invention. Facet fusion screw 420 is constructed of body 422, which defines a carrier receiving area 424. An end cap may be provided to seal the carrier receiving area, such as upper end cap 426. Upper end cap 426 is preferably provided with an injection port 428 to facilitate delivery of bone growth accelerant onto a carrier material for doping the carrier material that has been located within the carrier receiving area 424. Pathways or orifices 430 are provided in a location adjacent to vertebral facets 552a. Bone growth accelerant located within the carrier receiving 424 area migrates outwardly through pathways 430 into contact with adjacent vertebral facets 552a and promotes bone growth through pathways 430 to secure facet fusion screw 420 to the vertebrae, thereby immobilizing adjacent vertebrae with respect to one another. Facet fusion screw 420 is shown being

used in combination with spinal fusion cage 400 discussed above, to achieve a “360° fusion” of adjacent vertebrae 552. Although facet fusion screw is shown being used with spinal fusion cage 400, use of facet fusion screw 420 with other spinal fusion cages is also contemplated.

* * * * *

[0086] In addition to the interbody spinal fusions cages discussed above, further embodiments of applicant’s bone implantable device invention may take the form of a an IM nail 450 (FIG. 14), hip stem 500 (FIGs. 15, 16), artificial disk assembly 550 (FIGs. 17, 18), interbody graft 650 (FIGs. 22 - 24), bone fixation plates 700 (FIGs. 25 – 27), and other orthopedic appliances where promoting bone-to-bone growth or growth from bone into the device is beneficial.

EXAMPLE 2 – IM Nails

[0087] Referring now to FIG. 14, IM nail 450 is shown located in an interior cavity of femur 452. Femur 452 is shown with break 453. IM nail 450 has a body 451 and an end cap 454 that encloses carrier receiving area 456. Without end cap 454, a port is accessible for doping carrier material located in carrier receiving area 456. A plurality of pathways or orifices 458 communicates carrier receiving area 456 with an exterior of body 451. Preferably, IM stem 450 is carefully selected so that, upon placement within femur 452, orifices 458 are located adjacent break 453. By loading carrier receiving area 456 with a carrier and bone growth agent and locating orifices 458 adjacent break 453, improved mending of break 453 is facilitated.

EXAMPLE 3 – Hip Stems

[0088] Additionally, the bone implantable device of the invention may be fashioned into hip stem 500 (FIGs. 15, 16). Hip stem 500 is shown located in one end of

a femur **501**. Hip stem **500** has a body **502** defining a carrier receiving area **504** and a ball joint **505**. Preferably, carrier receiving area **504** is accessible via end cap **506**. End cap **506** is provided with injection port plug **508** for doping the carrier material. Carrier receiving area **504** is provided to receive a carrier **503** for bone growth agent. Pathways or orifices **510** allow bone growth agent to migrate from carrier receiving area **504** to an outside surface of body **502**. Additionally, bone growth will propagate through orifices **510** to assist in securing hip stem **500** within femur **501**.

EXAMPLE 4 – Artificial Disks

[0089] Referring back to FIGs. 17 and 18, an artificial disk assembly **550** is shown between two adjacent vertebrae **552**. Artificial disk assembly **550** includes an upper disk member **554** having a concave lower surface **556** and a perforated upper surface **558**. Perforated upper surface **558** has a plurality of pathways or orifices **560** formed therein. Preferably, upper disk member **554** defines a carrier receiving area **562**. Carrier receiving area **562** is accessible via a cap member **564**. Preferably, cap member **564** is provided with an injection port plug to facilitate doping of carrier material. Artificial disk assembly **550** additionally includes lower disk member **568** having a concave upper surface **570** and a perforated lower surface **572**. Perforated lower surface **572** has a plurality of pathways or orifices **574** (FIG. 18) formed therein. Preferably, lower disk member **568** defines a carrier receiving area **576**. Carrier receiving area **576** is accessible via a cap member **578**, which preferably receives an injection port plug **579** (FIG. 18) through which the carrier material may be doped. Concave surfaces **556** and **570** slidingly engage curved surfaces of artificial spinal disk **580**, which is preferably constructed of a polymer or other suitable material. Perforated surfaces **558** and **572** are located adjacent respective vertebrae **552**. Once a bone growth accelerant is injected onto

carrier material located within carrier receiving areas **562** and **576**, or as pre-loaded dissolvable carrier material is dissolved, the bone growth accelerator migrates into contact with vertebrae **552**. Bone material is then stimulated to grow through orifices **560** and **574** to secure the upper disk member **554** and lower disk member **568** to adjacent vertebrae **552**.

EXAMPLE 5 – Interbody Grafts

[0090] As a further example of a bone implantable device, an interbody graft **650** is shown in FIGs. 22 – 24. Interbody graft **650** may be inserted between adjacent vertebrae to facilitate fusion of the vertebrae. Interbody graft **650** is constructed of a ring shaped body defining an inner surface **651** and an annular carrier receiving area **652** for receiving carrier material **654**. Cap **656** is provided to access carrier receiving area **652**. Preferably, cap **656** is provided with an injection port **658** for facilitating doping carrier material **654**, i.e., for facilitating delivery of bone growth accelerator material onto carrier material **654**. A plurality of pathways or orifices **660** are provided on inner surface **651** for delivery of bone growth accelerator to adjacent bone material. As the bone growth accelerator passes through orifices **660**, adjacent bone structures are stimulated to grow into the opening defined by inner surface **651** where the two vertebrae fuse to one another.

EXAMPLE 6 – Bone Fixation Plates

[0091] As shown in FIGs. 25 – 27, a bone fixation plate **700** is another example of a bone implantable device of the invention. Bone fixation plate **700** may be used to assist in mending broken bones, such a collar bone **701**. Bone fixation plate **700** is provided with screw orifices **702** for receiving screws **704**. Screws **704** are used to affix bone fixation plate **700** to bone **701**. Bone fixation plate **700** defines a carrier receiving

area 706, which may be a hollow area within bone fixation plate 700 or may be a recessed area defined by bone fixation plate 700 as shown most clearly in FIG. 27. Carrier receiving area 706 is provided to receive carrier material 708 (FIG. 25) and to position carrier material 708 adjacent a desired bone structure. In this embodiment, carrier receiving area 706 also functions as a pathway to facilitate the delivery of bone growth accelerator to the bone structure. An injection port 712 may be provided to access carrier receiving area 706 so that bone growth accelerator may be carefully administered to the carrier after implantation of bone fixation plate 700, i.e., so that the carrier material 708 can be doped.

[0092] In each of the above described examples, a conveniently placed injection port provides the ability to deliver bone growth accelerator in a manner that reduces potential contact with non-target bone structures. The injection port is preferably located on the device body and communicates with a carrier material located in the carrier receiving area. The injection port facilitates delivery of bone growth accelerator to the carrier after implantation of the device. Alternatively, avoiding inadvertent contact with non-target bone structures may be achieved in each of the above examples by pre-loading devices with a dissolvable form of bone growth accelerator that liquefies after exposure to an implanted environment.

[0093] Preferably, the bone implantable device includes a carrier receiving area that may be a hollow interior structure in which carrier material is located. When utilizing an injection port, bone growth accelerator is injected into the carrier material through an injection port after implantation of the device. One or more apertures communicating with the carrier receiving area may be located on a portion of the device that is, upon implantation, adjacent target bone structure, which allows for controlled

delivery of bone growth accelerant to the target bone structure. A plenum may be provided in the carrier receiving area in an interior of the bone implantable device to facilitate the even distribution of bone growth accelerant from the injection port into the carrier material.

[0094] While the discussion has focused primarily on methods and devices for accelerating bone growth, it is contemplated that the devices and methods of the invention may also be used to deliver agents to other body structures including tendons and ligaments.

[0095] Finally, although the facet type screws discussed herein are shown facilitating the fusion of vertebral facets, it should be understood that the screws discussed herein may be useable in other ways and to fuse other bone structures besides vertebral facet structures discussed herein.

[0096] While the invention has been described with a certain degree of particularity, it is understood that the invention is not limited to the embodiment(s) set forth herein for purposes of exemplification, but is to be limited only by the scope of the attached claim or claims, including the full range of equivalency to which each element thereof is entitled.